



# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

re Application for:

Gary A. Beaudry et al.

Examiner: Carla J. Myers

Serial No.: 10/816,079

Group Art Unit: 1634

Filing Date: April 1, 2004

For: **COMPOSITIONS AND METHODS FOR THE IDENTIFICATION OF LUNG TUMOR CELLS**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313

## Certificate of First-Class Mailing (37 C.F.R. § 1.8(a))

I hereby certify that this paper and all enclosures are being deposited with the United States Postal Service as first class mail on the date indicated below in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Dated: 08/15/06

Name of Person Certifying: Taryn Antalek

Printed Name: Taryn Antalek

## INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. § 1.56, the references listed on the attached Form PTO-1449 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application.

### I. Timing of the Information Disclosure Statement:

This Information Disclosure Statement is filed:

- ☐ With the new patent application submitted herewith (37 C.F.R. § 1.97(a)).
- ☐ Within three months after the filing date of the application or within three months after the date of entry of the national stage of a PCT application as set forth in 37 C.F.R. § 1.491.
- ☒ Before the mailing date of a first Office Action on the merits. In the event, however, that an Office Action has crossed in the mail with this Information Disclosure Statement, the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for any fees required pursuant to 37 C.F.R. § § 1.17(p) or 1.17(i)(1).

This Information Disclosure Statement is filed:

- ☐ After the first Office Action and more than three months after the application's filing date; or PCT national stage date of entry filing but, as far as is known to the undersigned, prior to the mailing date of either a final rejection or a notice of allowance, whichever comes first, and the Commissioner is hereby authorized to charge Deposit Account No. 07-1074 for the fee (\$180.00) set forth in 37 C.F.R. § 1.17(p) and any additional required fees.

This Information Disclosure Statement is filed:

- ☐ After the mailing date of either a final rejection or a notice of allowance, whichever occurred first, and is accompanied by the fee (\$180.00) set forth in 37 C.F.R. § 1.17(i)(1) and a certification as specified in 37 C.F.R. § 1.97(e), as checked below. This document is to be considered as a petition requesting consideration of the Information Disclosure Statement.

The undersigned certifies that:

- ☐ Each item of information contained in the Information Disclosure Statement was first cited in any communication mailed from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this information disclosure statement.
- ☐ No item of information contained in this information disclosure statement was cited in a communication mailed from a foreign patent office in a counterpart foreign application or, to the knowledge of the undersigned after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56 more than three months prior to the filing of this Information Disclosure Statement.

## **II. Copies of the Cited Items:**

- ☐ Copies of all of the items listed on the attached Form PTO-1449 are enclosed.
- ☐ Copies of only the following items listed on the attached Form PTO-1449 are not enclosed:
- ☒ Copies of those items which are NOT marked with an asterisk (\*) in the attached Form PTO-1449 are not supplied because they were previously cited by or submitted to the Patent Office in a prior Application No. 09/663,516 filed September 15, 2000 and relied upon in this application for an earlier filing date under 35 U.S.C. § 120. See 37 C.F.R. § 1.98(d).

- ☐ Copies of those items which are marked with an asterisk (\*\*) in the attached Form PTO-1449 were cited in a foreign examination report in a related case. A copy of the search report and the cited references not already of record in this application are attached hereto.

### III. Concise Explanation of Relevance:

Citation of the above documents shall not be construed as:

1. an admission that the documents are necessarily prior art with respect to the instant invention;
2. a representation that a search has been made, other than as described above; or
3. an admission that the information cited herein is, or is considered to be, material to patentability as defined in §1.56(b).

It is respectfully requested that the Examiner indicate consideration of the cited references by returning a copy of the attached form PTO 1449 with initials or other appropriate marks.

The Commissioner is hereby authorized to charge Deposit Account No. **07-1074** for any additional fees required in connection with the filing of this Information Disclosure Statement.

8/15/06

Date

Respectfully submitted,

By: 

Jennifer D. Tousignant  
Agent for Applicants  
Registration No. 54,498

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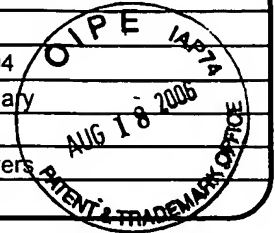
## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

*(Use as many sheets as necessary)*

Sheet	1	of	4
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**Complete if Known**

<b>Application Number</b>	10/816,079
<b>Filing Date</b>	April 1, 2004
<b>First Named Inventor</b>	Beaudry, Gary
<b>Art Unit</b>	1634
<b>Examiner Name</b>	Carla J. Myers
<b>Attorney Docket Number</b>	GA0129C2



## U.S. PATENT DOCUMENTS

[illegible]

## FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> - Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
	5	WO 89/06703	07/17/89	Dryja et al.		
	6	WO 89/09818	10/19/89	Biogen, Inc.		
	7	WO 90/05745	05/31/90	General Hospital Corp.		
	8	WO 97/12975	04/10/97	United States of America		
	9	WO 97/42211	11/13/97	Chiron Corp.		

Examiner  
Signature

Date Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.<sup>1</sup> Applicant's unique citation designation number (optional).<sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 2 of 4

**Complete if Known**

Application Number	10/816,079
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First Named Inventor	Beaudry, Gary
Art Unit	1634
Examiner Name	Carla J. Myers
Attorney Docket Number	GA0129C2

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	10	Oda, T. et al., "Cloning of the Human alpha-Catenin cDNA and its Aberrant mRNA in a Human Cancer Cell Line," Biochemical and Biophysical Research Communications, June 1993, 193(3):897-904.	
	11	Patel, S. et al., "Expression and Purification of the Canine 54-kDa Subunit of Signal Recognition Particle as a His-Tagged Protein from Escherichia coli," Protein Expression and Purification, June 1996, 8(3):283-294.	
	12	Derisi J. et al., "Use of a cDNA microarray to analyze gene expression patterns in human cancer," Nature Genetics, December 1996, 11:457-460.	
	13	Bullions, L. et al., "Expression of Wild-Type alpha-Catenin Protein in Cells with a Mutant alpha-Catenin Gene Restores Both Growth Regulation and Tumor Suppressor Activities," Molecular and Cellular Biology, August 1997, 17(8):4501-4508.	
	14	Romisch, K. et al., "Homology of 54K protein of signal-recognition particle, docking protein and two e. coli proteins and putative GTP-binding proteins," Nature, August 1989, 340(6233):478-482.	
	15	DATABASE EMBL ONLINE, E.B.I. Hinxton, Accession Number: D13866, 11 December 1994, Oda. T. et al., "Human mRNA for alpha-catenin."	
	16	DATABASE EMBL ONLINE, E.B.I. Hinxton, Accession Number: X16318, 23 November 1989, Romisch et al., Canine mRNA for signal recognition particle 54k protein."	
	17	DATABASE EMBL ONLINE, E.B.I. Hinxton, Accession Number: X86373, 20 April 1995, Patel et al., "Homo sapiens SRP54 complex DNA."	
	18	DATABASE EMBL ONLINE, E.B.I. Hinxton, Accession Number: AA484483, NCI-CGAP, "Homo sapiens cDNA clone IMAGE:913139, mRNA sequence."	
	19	DATABASE EMBL ONLINE, Accession Number: N94741, 19 April 1996, Hillier et al., "Soares_parathyroid_tumor_NbHPA Homo Sapiens cDNA clone IMAGE:305326 3,' mRNA sequence."	
	20	DATABASE EMBL ONLINE, Accession Number: AA009830, 2 August 1996, Hillier et al., "Soares_fetal_liver_spleen_1NFLS_S1 Homo sapiens cDNA clone IMAGE:430068 3,' mRNA sequence."	

Examiner  
SignatureDate  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached.

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Sheet 3 of 4

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Attorney Docket Number	GA0129C2

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	21	Bacher, N. et al., "Isolation and Characterization of PKC-L, A New Member of the Protein Kinase C-Related Gene Family Specifically Expressed in Lung, Skin and Heart," Molecular and Cellular Biology, January 1991, 11(1):126-133.	
	22	DATABASE GENBANK, E.B.I. Hinxton, Accession Number: X52973, 17 February 1997, Zschunke, F. et al., "Serine Esterase."	
	23	DATABASE GENBANK, E.B. Hinxton, Accession Number M55509, 27 April 1993, Long, R.M. et al., "Human Liver Carboxylesterase."	
	24	DATABASE GENBANK, E.B. Hinxton, Accession Number: X04972, 18 May 1994, Hallewell, R.A. et al., "Mouse Manganese Superoxide Dismutase."	
	25	Van Zandwijk et al., "The role of prognostic factors and oncogenes in the detection and management of Non-Small-Cell Lung Cancer," Oncology, January 1998, Supplement 2, 55-59.	
	27	Salgia R. and Skarin, A., "Molecular Abnormalities in Lung Cancer," Journal of Clinical Oncology, March 1998, 16(3):1207-1217.	
	28	Birrer, M.J. and Brown, P.H., "Application of molecular genetics to the early diagnosis and screening of lung cancer," Cancer Research, May 1992, 52:2658s-2664s.	
	29*	Yamamoto, M. et al. "Use of serial analysis of gene expression (SAGE) technology," Journal of Immunological Methods, vol. 250, 2001 pp. 45-66.	
	30*	Hibi, K. et al. "Serial analysis of gene expression in non-small cell lung cancer." Cancer Research, vol 58, Dec. 1998 (1998-12), pp. 5690-5694.	
	31*	Lipshutz et al. Using Oligonucleotide Probe Arrays to Access Genetic Diversity, Biotechniques 1995, vol. 19 #3, pp. 442-447.	
	32*	Zschunke F, Blood. cDNA cloning and characterization of human monocyte/macrophage serine esterase-1. (1991), vol. 78 #2.	

Examiner Signature		Date Considered	
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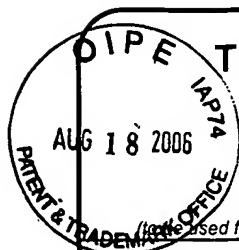
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# TRANSMITTAL FORM

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Application Number

10/816,079

Filing Date

April 1, 2004

First Named Inventor

Beaudry, Gary

Art Unit

1634

Examiner Name

Carla J. Myers

Attorney Docket Number

GA0129C2

## ENCLOSURES (check all that apply)

☐ Fee Transmittal Form☐ Fee Attached☐ Amendment / Reply☐ After Final☐ Affidavits/declaration(s)☐ Extension of Time Request☐ Express Abandonment Request☒ Information Disclosure Statement

(3 sheets)

☐ Certified Copy of Priority Document(s)☐ Reply to Missing Parts/  
Incomplete Application☐ Reply to Missing Parts  
under 37 CFR 1.52 or 1.53☐ Drawing(s)☐ Licensing-related Papers☐ Petition☐ Petition to Convert to a  
Provisional Application☐ Power of Attorney, Revocation  
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(Appeal Notice, Brief, Reply Brief)☐ Proprietary Information☐ Status Letter☒ Other Enclosure(s)  
(please identify below):PTO Form 1449 (4 sheets); copies of  
seven (7) cited references and return  
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Remarks

## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm

GENZYME CORPORATION

Signature

Printed Name

Jennifer D. Tousignant

Date

8/15/06

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54,498

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Date

08/15/06

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